Cooperative Research and Development Agreement (CRADA) -
Health Effects of RF Emissions from Wireless Phones (Mobile Units for Commercial Mobile Radio Services)

Abstract/Summary of Proposed Agreement

The initial work of the CRADA is to focus on two study topics -- mechanistic studies related to genotoxicity, and epidemiologic studies -- and to mutually assess areas of further research in order to contribute to the assessment of the possible health effects of RF emissions from wireless phones (mobile units for commercial mobile radio services). CDRH will provide scientific and technical advice on issues to be addressed and studies that should be performed. As needed, CDRH will obtain input from government, industry, and private scientific and technical experts. In order to avoid unnecessary duplication and in recognition of the international nature of the scientific community and of the wireless industry, any recommendations for further study will consider the scientific literature and ongoing research from an international perspective. CTIA will directly administer research conducted by third parties. Consistent with Article 8.7 of the CRADA, it is the intent of the parties that research results will be made publicly available, *e.g.*, through publication in the peer-reviewed scientific literature or other appropriate means. CTIA will provide support to CDRH for the activities it must undertake to carry out its role in this CRADA. CTIA will provide travel expenses and honoraria for scientific and technical experts to participate in review meetings and to review research progress.

Appendix A

Research Plan

Title of CRADA: Health Effects of RF Emissions from Wireless Phones (Mobile Units for Commercial Mobile Radio Services)

FDA Principal Investigator: Russell D. Owen

Laboratory: Radiation Biology Branch, Division of Life Sciences, Office of Science and Technology, Center for Devices and Radiological Health, Rockville, MD 20850

Collaborator Principal Investigator: Jo-Anne Basile

Term of CRADA: Date of execution of the CRADA to December 31, 2002

1.0 Introduction

Over 82 million people in the United States alone were mobile phone users in December 1999, according to the Cellular Telecommunications Industry Association website. Tens of thousands of new users are being added every day. With the widespread use of wireless phones, a relatively newly deployed technology, FDA, as a public health agency, has a role to monitor developments in radiofrequency energy (RF) research relevant to health effects. The research database on RF should be more fully developed to continually evaluate whether this exposure poses any adverse health effects.

1.1 Goals

Currently the scientific literature relating to the health effects of low level exposure to RF does not demonstrate the existence of any health risk from wireless phones, i.e., mobile units for commercial mobile radio services (CMRS). Little is known, however, about the possible health effects of repeated or long-term exposure to low level RF of the sort emitted by mobile units for CMRS. Some studies suggest the possibility for such low-level exposures to increase the risk of adverse health effects by unknown mechanisms. Other studies, however, have not confirmed the existence of such risks. Research is needed to support a risk assessment of the health effects of RF emissions from mobile units for CMRS. The processes set forth in this CRADA are intended to ensure that the ensuing research is conducted in a way that promotes quality, scientific independence, integrity, and efficiency.

1.2 Scope

The initial work of this CRADA will entail a process of scientific oversight and research recommendations to address the results of studies previously conducted by the Wireless Technology Research, L.L.C. (WTR) which raised scientific questions. Accordingly, this

CRADA will focus on two topics: (a) mechanistic studies related to genotoxicity (or carcinogenesis) and (b) research on additional epidemiologic studies. The Center for Devices and Radiological health (CDRH) will provide scientific and technical advice on the studies that are needed. Based on the CDRH recommendations, the Cellular Telephone Industry Association (CTIA) will directly contract with third parties to perform research. The parties agree that third party research studies will not be conducted pursuant to this CRADA, but rather under separate agreements with the relevant parties. CTIA will give third party research investigators a copy of the CRADA and explain the role of CDRH in providing recommendations for research. As outlined in Article 4.1, CTIA and CDRH as parties to the CRADA will exchange interim progress reports on a mutually agreed upon schedule. Consistent with Articles 8.2 to 8.6 of this CRADA, the parties will treat such reports and the ongoing working data of the third party research investigators as confidential. Consistent with Article 8.7, it is the intent of the parties that research results, when the research is complete, will be made publicly available, *e.g.*, through publication in the peer-reviewed scientific literature or other appropriate means. The work of this CRADA will also entail (c) a mutual assessment of future study topics, wherein issues identified in implementing the initial studies and any future study topics will be evaluated in the context of ongoing developments in global research on health effects of RF emissions from mobile units for CMRS.

(a) Genotoxicity Study

The purpose of this study is to follow up on the findings of the previously conducted WTR studies using the micronucleus assay. Potential issues to be addressed include the accuracy and reproducibility of the WTR results, the critical parameters upon which these results depend, and exposure dosimetry.

(b) Epidemiology Study

The purpose of this study is to follow up on the findings of the WTR cohort and case control studies. The initial goals are to identify the type of follow up research that is warranted, and to establish the relative priority of warranted studies. Potential issues to be addressed include the type of follow up studies required to address pertinent unanswered questions, whether additional information is necessary to perform such an evaluation, and whether an additional case control study is required. The need for participation in a multi-center case control study (such as that being coordinated by International Agency for Research on Cancer) and the need for an additional cohort study will also be evaluated.

(c) Assessment for Future Study Topics

Topics for further consideration will be selected by mutual consent of CDRH and CTIA. In order to avoid unnecessary duplication and in recognition of the international nature of the scientific community and of the wireless industry, any recommendations for study will consider the scientific literature and ongoing research from an international perspective. This could be achieved through consultation with organizations around the

world engaged in review and research on the health effects of R-F emissions and mobile units for CMRS (e.g., the World Health Organization International EMF Project).

1.3 General approach

In considering the initial two topics for study designated in this CRADA, as well as the further topics as may be agreed upon for further research, CDRH will review the available scientific research, identify the scientific issues of merit and propose the research to address them, and provide recommendations on the conduct of appropriate studies. In consideration of the recommendations from CDRH and the constraints of the CTIA budget, CTIA will contract for the conduct of the research. CTIA will issue a request for proposals (RFP) (or a similar method) to third parties interested in conducting the studies. CDRH will review the proposals received in response to the request for responsiveness to the research needs. CTIA will review the budgetary feasibility of the proposals and select the proposal(s) to be funded. A brief technical description of the proposals will be prepared and be available for public disclosure. CTIA will directly administer the funding of the research, which funds will be provided through individual research contracts specifying budgets and completion dates. CDRH will evaluate the conduct of such research, review the results obtained, and discuss its assessment with CTIA. It is the intent of CDRH throughout this process to obtain outside input that comprises the best available scientific and technical expertise. CDRH will obtain input from government, industry, and private scientific and technical experts (e.g., through meetings). CTIA will also provide travel expenses and honoraria for scientific and technical experts to participate in review meetings and to review research progress.

2.0 Projected Work Schedule

The work described above is expected to require a three-year effort. The agreement will become effective upon execution. Progress reports will be exchanged annually or more frequently, as necessary.

2.1 Year One

(a) Genotoxicity Study

CDRH will form an Organizing Committee, predominantly composed of staff from CDRH and other federal agencies. With this committee, CDRH will select a Working Group made up of scientific and technical experts from government, industry, and academic institutions. This Working Group will meet to review the available data and will develop a statement of work describing the research needs in detail. CTIA will issue a request for proposals based on the statement of work. CDRH, with the Working Group, will review the proposals and make recommendations to CTIA regarding the scientific merit of the proposals. CTIA will review the proposal budgets and select the proposal(s) to be funded.

(b) Epidemiology Study

CDRH will form an Organizing Committee, predominantly composed of staff from CDRH and other federal agencies. With this committee, CDRH will select a Working Group made up of scientific and technical experts from government, industry, and academic institutions. A meeting of the Working Group will be convened to identify issues in epidemiology research and to assess whether any new or follow-up epidemiological studies are warranted.

(c) Assessment for Future Study Topics

The CRADA partners will make plans for convening technical and scientific experts to review global research and develop research recommendations.

2.2 Year Two

(a) Genotoxicity Study

CDRH and CTIA, with the help of the Working Group, will review contractor progress and results.

(b) Epidemiology Study

If it is determined that follow-up work in epidemiology is warranted, the Working Group will develop a statement that reflects the research to be undertaken. CTIA will issue a request for proposals based on the statement of work. CDRH, with the Working Group, will review the proposals and make recommendations to CTIA regarding the scientific merit of the proposals. CTIA will review the proposal budgets and select the proposal(s) to be funded.

(c) Assessment for Future Study Topics

CDRH will form an Organizing Committee, predominantly composed of staff from CDRH and other federal agencies. With this committee, CDRH will select a Working Group made up of scientific and technical experts from government, industry, and academic institutions. A meeting or series of meetings will be held to comprehensively review the ongoing global research and to identify and prioritize further research that is not being addressed by that research.

2.3 Year Three

(a) Genotoxicity Study

CDRH and CTIA, with the help of the Working Group, will review contractor progress and results.

(b) Epidemiology Study

CDRH and CTIA, with the help of the Working Group, will review contractor progress and results.

(c) Assessment for Future Study Topics

The CRADA partners will review the research identified by the Working Group and consider study topics of mutual interest for future collaborative research, if any.